K032971

AUG 2 6 2004

510(K) SUMMARY

September 3, 2003

a. Applicant's Name and Address

Respironics Novametrix, Inc.
5 Technology Drive
Wallingford, CT 06492

b. Contact Person

Michael J. Malis
Q.A. and Regulatory Manager
(203) 697-6442
(203) 284-0753 (facsimile)

c. Name of Device

Device Names (Proprietary/Trade Names):	Tidal Wave Sp, Models 710/715
Device Name (Common Name):	pulse oximeter/carbon dioxide monitor
Classification:	Class II, 21 C.F.R. 870.2700 Class II, 21 C.F.R. 868.1400

Equivalent Devices

Substantial equivalence to the following legally marketed predicate devices with the same or similar indications for use has been demonstrated by a comparison of product features as described in the labeling and promotional literature for the Model 512/513, and TidalWave Model 610 as well as testing to accepted industry standards. In addition, inter-device comparison studies were conducted to establish the TidalWave Sp accuracy and to ensure that the sensors meet their currently published accuracy specifications with the specified predicate devices. The predicate devices are as follows:

1. Tidal Wave Model 610 (510(k) No. K963327) dated 11/20/1996
2. CO_2SMO, Model 7100 (510(k) No. K920379/A), dated 07/15/1992
3. Spot Check Model 510 (510(k) No. K924626), dated 12/03/1993.

e. Device Description

The Tidal Wave Models 710/715 handheld combined pulse oximeter/capnograph are designed for continuous, non-invasive monitoring of carbon dioxide and functional oxygen saturation. Oxygen saturation is measured with ratiometric technique using red and infrared absorbance of oxy- and deoxyhemoglobin and pulse rate is measured using the time between successive pulses. Carbon dioxide is measured on-airway using an infrared absorption (IR) technique. The airway adapters and O_2 saturation sensors are already legally marketed as accessories to the Model 610 and Model 510 monitors, respectively. The TidalWave Sp monitor is a microprocessor based data acquisition system consisting of CO_2 and SpO_2 measurement, control circuitry and a high speed serial interface. The monitor uses SRAM for data storage and an EEPROM to store system parameters. The firmware resides in a PROM. The operations performed by the TidalWave Sp monitor include data acquisition, parameter calculation, zeroing, heater control and corrections to the CO_2 signal for N_2O, O_2 and barometric pressure.

f. Intended Use

The intended use of the TidalWave Sp (Models 710/715) is to provide short term monitoring of carbon dioxide and oxygen saturation during anesthesia / recovery, in the intensive care unit (ICU), and in Emergency Medicine/Transport or Respiratory care. Separate airway adapters are provided for pediatric/adult and neonatal/pediatric use. The TidalWave Sp (Models 710/715) and its airway adapters and sensors are intended to be used by trained operators when capnographic and/or pulse oximetry monitoring is required in the judgement of a physician. The intended use, patient population and environments of use are the same or similar to the predicate devices

g. Technological Characteristics

The TidalWave Sp is a combination of the current Novametrix Tidal Wave capnography and Model 510 pulse oximeter. As with the Tidal Wave, the TidalWave Sp measures CO2 with the Capnostat CO2 sensor. In mainstream mode the Capnostat sensor attaches to an airway adapter (also referred to as a cuvette) and in which the patient's inspired and expired breath passes. The airway adapter is attached to a mouthpiece or mask, or to the breathing circuit between the endotracheal tube and ventilator circuit wye, if the patient is intubated. It is designed to use neonatal and adult CO2 airway adapters. In sidestream mode, a sample from the patient is drawn into a sidestream cuvette attached the TidalWave Sp monitor to which the Capnostat is affixed to. The pulse oximetry parameters which are directly measured and computed by the TidalWave Sp include oxygen saturation and pulse rate.

The TidalWave Sp uses an infrared absorption (IR) technique for monitoring CO2. IR based methods have endured and evolved in the clinical setting for over two decades, and remain the most popular and versatile technique today. The principle is based on the fact that CO2 molecules absorb infrared light energy at specific wavelengths, with the amount of energy absorbed being directly related to the CO2 concentration. When the IR light beam is passed through a gas sample containing CO2, the electronic signal from the photodetector can be obtained. This signal is then compared to the energy of the IR source, and calibrated to accurately reflect CO2 concentration in the sample. To calibrate, the photodetector's response to a known concentration of CO2 is stored in the monitor at the factory.

The TidalWave Sp measures oxygen saturation and pulse rate with sensors that contain red and infrared light sources. Since oxygen saturated blood absorbs different amounts of light at each wavelength (red and infrared) as compared with unsaturated blood, the amount of light absorbed at each wavelength by the blood in each pulse can be used to calculate oxygen saturation. The light energy from red (660 nm) and infrared (940 nm) LEDs is beamed through a sample cell- a pulsating vascular bed, the patient's finger or toe for example. The remaining light energy not absorbed by the sample cell reaches a photodiode, on the opposing side of the sensor. The signal received by the photodiode is split into its red and infrared components, sampled, software filtered, and displayed as a numerical value for functional oxygen saturation and as a waveform, the plethysogram.

Pulse rate is calculated by measuring the time interval between the peaks of the infrared light waveform. The Models 710/715 use the identical SpO_2 and pulse rate software algorithms to process the information from the sensor as the predicate device, Model 510 Pulse Oximeter, cleared under K924626.

h. Certification Statement

In accordance with the requirements of 21 CFR 807.87(j), the following certification is provided:

Respironics Novametrix, Inc. believes that all data and information submitted in this premarket notification are truthful and accurate and no material fact has been omitted.

Michael J. Malis
Q.A. and Regulatory Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 6 2004

Mr. Michael J. Malis
Quality Assurance and Regulatory Manager
Respironics Novametrix, Incorporated
5 Technology Drive
Wallingford, Connecticut 06492

Re: K032971
Trade/Device Name: Tidal Wave SP, Model 710/715
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: August 20, 2004
Received: August 23, 2004

Dear Mr. Malis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

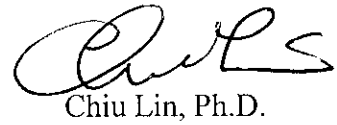
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K032971

Device Name: TidalWave Sp, Model 710/715

Indications For Use:

The intended use of the TidalWave Sp (Models 710/715) is to provide short term monitoring of carbon dioxide and oxygen saturation during anesthesia / recovery, in the intensive care unit (ICU), and in Emergency Medicine/Transport or Respiratory care. Separate airway adapters are provided for pediatric/adult and neonatal/pediatric use.

Prescription Use X **OR** **Over-The-Counter Use** _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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